IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

NO. 7:10-CV-173-FL

LISSA M. ROHLIK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	ORDER
	)	
I-FLOW CORPORATION,	)	
	)	
Defendant.	)	

This matter comes before the court upon defendant's motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure (DE # 12). Plaintiff responded in opposition, and defendant timely replied. In this posture, the issues raised are ripe for adjudication. For the reasons that follow, defendant's motion to dismiss is granted in part and denied in part.

STATEMENT OF THE CASE

Plaintiff filed complaint on September 3, 2010, alleging that a pain pump manufactured by defendant, used by plaintiff following arthroscopic surgery on her left shoulder in December 2006, caused her to develop chondrolysis.[1] The complaint contains a number of causes of action arising under state law, including negligence, negligent misrepresentation, fraud, breach of implied warranty, breach of express warranty, and unfair and deceptive trade practices. Plaintiff seeks compensatory and punitive damages, disgorgement of profits, and attorneys' fees.

[1] According to the complaint, pain pumps are medical devices used to manage post-operative pain. The pain pump at issue here delivered continuous doses of anesthetics directly into plaintiff's shoulder joint following surgery. Plaintiff alleges that the anesthetics killed the cartilage cells (*i.e.*, chondrocytes) in plaintiff's shoulder, leading to the complete nearly complete loss of cartilage in the joint (*i.e.*, chondrolysis).

On November 3, 2010, prior to filing answer, defendant moved to dismiss the negligent misrepresentation, fraud, and unfair and deceptive trade practices claims, as well as plaintiff's request for punitive damages. Defendant also seeks to strike plaintiff's request for attorneys' fees. Plaintiff responded in opposition on November 23, 2010, and defendant timely replied on December 21, 2010. After United States Senior District Judge James C. Fox recused himself due to a possible conflict of interest, the motion was referred to the undersigned on June 20, 2011.

STATEMENT OF THE FACTS

The factual allegations relevant to defendant's motion to dismiss, viewed in the light most favorable to plaintiff, are set forth below. Additional factual allegations relevant to the court's analysis are discussed as necessary throughout this order.

In April 2006, plaintiff consulted Dr. David A. Esposito ("Dr. Esposito"), an orthopedic surgeon, regarding a problem with her left shoulder. On December 19, 2006, after months of more conservative treatment, plaintiff underwent routine arthroscopic surgery. Dr. Esposito employed a pain pump manufactured by defendant to manage plaintiff's post-operative pain. The pain pump injected anesthetics on a continuous basis into plaintiff's shoulder joint through a catheter.

Following the initial healing process, plaintiff began to experience pain as well as clicking and popping noises in her left shoulder. On December 18, 2007, plaintiff underwent a second arthroscopic surgery. Dr. Esposito diagnosed plaintiff with chondromalacia.[2] On March 8, 2010, plaintiff consulted with Dr. Alison P. Toth ("Dr. Toth") of Duke University Medical Center. Dr. Toth diagnosed plaintiff as suffering from chondrolysis related to the use of a pain pump.

[2] Although not defined in the complaint, chondromalacia is defined elsewhere as a softening of the cartilage within a joint. See Dorland's Illustrated Medical Dictionary 358 (31st ed. 2007) (defining chondromalacia as "softening of the articular cartilage, most frequently in the patella").

According to plaintiff, defendant knew about the danger of using pain pumps in a joint space on or before the date of plaintiff's surgery. In fact, plaintiff alleges that defendant and its agents misled the medical community and the public by making false representations about the safety of pain pumps used in this manner. Plaintiff specifically references (1) the alleged denial in 1998 of defendant's application for approval to market their pain pumps for orthopedic and intra-articular (*i.e.*, within the joint space) use by the Food and Drug Administration ("FDA"); (2) defendant's subsequent marketing efforts to promote this off-label use of pain pumps; (3) reports of chondrolysis in pain pump users received by defendant beginning in July 2004 and continuing through September 2006; and (4) the withholding by defendant, until September 2007, of a technical bulletin prepared a year earlier regarding chondrolysis.

DISCUSSION

A. Standard of Review

A motion to dismiss under Rule 12(b)(6) determines only whether a claim is stated. Republican Party v. Martin, 980 F.2d 943, 952 (4th Cir. 1992). A claim is stated if the complaint contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In evaluating whether a claim is stated, "[the] court accepts all well-pled facts as true and construes these facts in the light most favorable to the plaintiff," but does not consider "legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement." Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009). Nor will the court accept as true "unwarranted inferences, unreasonable conclusions, or arguments." Wahi v. Charleston Area Med. Ctr., Inc., 562 F.3d 599, 615 n.26 (4th Cir. 2009).

B. Analysis

The court begins by noting that defendant does not challenge, under Rule 12(b)(6), the claims of negligence, breach of implied warranty, and breach of express warranty asserted in the complaint. Accordingly, these claims will not be subject to further discussion in this order, and plaintiff will be allowed to proceed with them.

1. Fraud and Negligent Misrepresentation

Defendant challenges plaintiff's negligent misrepresentation and fraud claims on two grounds. First, it contends that plaintiff has not pleaded the circumstances of the relevant misrepresentations with particularity, as required by Rule 9(b). Second, it contends that plaintiff's claims are preempted by federal law. Because the court finds that plaintiff's complaint fails to meet the requirements of Rule 9(b), it does not address defendant's preemption argument.

Where a plaintiff pleads fraud, Rule 9(b) requires her to "state with particularity the circumstances constituting fraud . . . ." See Fed. R. Civ. P. 9(b). "[C]laims of negligent misrepresentation [also] fall within the purview of Rule 9(b)." Dealer's Supply Co., Inc. v. Cheil Indus., Inc., 348 F. Supp. 2d 579, 590 (M.D.N.C. 2004). "[T]he circumstances required to be pled with particularity under Rule 9(b) are the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999); see also Food Lion, LLC v. Schuster Mktg. Corp., 382 F. Supp. 2d 793, 797 (E.D.N.C. 2005) (applying Harrison to a North Carolina common law fraud claim). Under North Carolina law, a plaintiff alleging fraud must also "allege[] detrimental reliance, and damages proximately flowing from such reliance, with particularity." Frank M. McDermott, Ltd. v. Moretz, 898 F.2d 418, 421 (4th Cir. 1990).

Plaintiff's complaint contains a number of general allegations of misrepresentations to "the public" and "physicians," none of which were specifically directed at plaintiff or Dr. Esposito. For example, she alleges that defendant falsely claimed FDA approval for its pain pumps in 1998 and marketed those pain pumps for intra-articular use knowing that they were not safe for such use. Plaintiff provides examples of these misrepresentations, including brochures in physician's offices, incentive programs and giveaways, and PowerPoint presentations. What plaintiff does not do, and what is required by Rule 9(b), is allege that plaintiff and Dr. Esposito were exposed to these materials, when they were exposed to them, and that they relied upon them in deciding to use a pain pump following plaintiff's shoulder surgery.

The closest plaintiff comes to asserting a fraud or negligent misrepresentation claim is her discussion of Tate Carter ("Carter"), a sales representative working for defendant.[3] Plaintiff states that Carter actively "marketed" defendant's pain pumps to Dr. Esposito without providing any warnings that the pain pump was not approved for intra-articular use or that they could cause damage to a patient's cartilage. Plaintiff also alleges that Carter was present in the operating room during plaintiff's surgery on December 19, 2006, instructed Dr. Esposito and his nurses on how to fill the pain pump, and watched Dr. Esposito affix the pain pump to plaintiff's shoulder.

Although these allegations show some interaction between defendant's agent and plaintiff and her surgeon, no specific misrepresentations are identified. Plaintiff provides a conclusory

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[3] The elements of a North Carolina fraud claim are "(1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party." Forbis v. Neal, 361 N.C. 519, 526-27, 649 S.E.2d 382, 387 (2007). "Additionally, any reliance on the allegedly false representations must be reasonable." Id. at 527, 649 S.E.2d at 387. The elements of a negligent misrepresentation claim are (1) justifiable reliance (2) to a party's detriment (3) on information prepared without reasonable care (4) by one who owed the relying party a duty of care. Raritan River Steel Co. v. Cherry, Bekaert & Holland, 322 N.C. 200, 206, 367 S.E.2d 609, 612 (1988).

statement that Carter "made material misrepresentations and concealments to Dr. Esposito" and that the doctor "justifiably relied" on these misrepresentations, without actually informing defendant what it is that Carter allegedly said to Dr. Esposito (beyond instructing him how to fill the pain pump, which presumably was not a "false" statement in and of itself). Did Carter tell Dr. Esposito that defendant's pain pump had been approved by the FDA for intra-articular use? Did he tell Dr. Esposito that it had been found harmless for such use in numerous studies? Was there a conversation regarding the safety of using defendant's pain pumps in a joint space during which Carter kept mum? Without such an allegation, plaintiff has not satisfied the strict "who, what, where, when, why, and how" requirement of Rule 9(b).

To assert a fraud or negligent misrepresentation claim, plaintiff must do more than simply allege that defendant engaged in a marketing program containing misrepresentations, of which plaintiff and her surgeon may or may not have been aware of, and that a sales representative marketing defendant's product taught plaintiff's surgeon how to fill a pain pump and watched him affix it to her.[4] The specific allegations required by Rule 9(b) and North Carolina law are missing from the complaint. Accordingly, defendant's motion to dismiss these claims is granted.

2. Unfair and Deceptive Trade Practices

Defendant argues that plaintiff has not properly asserted a claim under the Unfair and Deceptive Trade Practices Act ("UDTPA"), N.C. Gen. Stat. § 75-1.1. According to defendant, plaintiff has not alleged any egregious or aggravating circumstances, and her UDTPA claim is

[4] The court also notes that there is nothing inherently fraudulent or misleading about promotion of off-label uses for medical devices. See In re Actimmune Mktg. Lit., 614 F. Supp. 2d 1037, 1051 n.6 (N.D. Cal. 2009); United States v. Caronia, 576 F. Supp. 2d 385, 397 (E.D.N.Y. 2008). "Once the FDA has cleared a device for introduction into the stream of commerce, physicians may use the device in any manner they determine to be best for the patient, regardless of whether the FDA has approved the device for this usage." Cooper v. Smith & Nephew, Inc., 259 f.3d 194, 197 (4th Cir. 2001).

indistinguishable from her breach of warranty claims. Because plaintiff's UDTPA claim is the only claim identified by plaintiff for which an award of attorneys' fees may be appropriate, see N.C. Gen. Stat. § 75-16.1, defendant asks the court to strike plaintiff's request for attorneys' fees under Rule 12(f) upon dismissal of this claim.

To state a claim under the UDTPA, a plaintiff must allege (1) an unfair or deceptive act or practice, (2) in or affecting commerce, (3) that proximately caused actual injury to plaintiff. See Dalton v. Camp, 353 N.C. 647, 656, 548 S.E.2d 704, 711 (2001). "A practice is unfair if it is unethical and unscrupulous, and it is deceptive if it has a tendency to deceive." Id. This court, applying North Carolina law, recently held that "a breach of warranty alone is insufficient to state a UDTPA claim." Kelly v. Georgia-Pacific LLC, 671 F. Supp. 2d 785, 799 (E.D.N.C. 2009). Instead, in order to assert a claim under the UDTPA in a breach of warranty case, "a party must allege some type of egregious or aggravating circumstances," and must show "actual reliance" on any misrepresentation.[5] Id.

The complaint in this matter does not contain allegations of substantial aggravating circumstances unlocking the extraordinary treble damages provision of the UDTPA. Plaintiff's allegations that defendant represented that the pain pump used by plaintiff was free from defects and safe for use, even if defendant knew the pain pump would not conform to these promises, is indistinguishable from a run-of-the-mill breach of warranty claim. Moreover, as previously noted, plaintiff has not identified any specific misrepresentation by defendant, beyond the warranty itself,

[5] The Fourth Circuit has warned against allowing plaintiffs to "attempt . . . to manufacture a tort dispute" out of such claims. See Strum v. Exxon Co., 15 F.3d 327, 329 (4th Cir. 1994). That court has identified North Carolina's UDTPA as a "boilerplate claim in most every complaint based on a commercial or consumer transaction in North Carolina," frequently asserted in an effort to obtain the extraordinary damages authorized by the act. See Broussard v. Meineke Disc. Muffler Shops, Inc., 155 F.3d 331, 347 (4th Cir. 1998).

that was relied upon by plaintiff or her physician. Even assuming defendant engaged in a nation-wide campaign marketing its pain pumps for an unapproved and harmful use, plaintiff may not invoke the UDTPA without alleging that she was aware of this campaign when she used the offending product.

Because plaintiff's UDTPA claim is indistinguishable from her breach of warranty claims, defendant's motion to dismiss as to the UDTPA claim is granted. Moreover, because the UDTPA is the only claim identified by plaintiff as to which attorneys' fees are appropriate, the court may strike this request from the complaint. See Fed. R. Civ. P. 12(f) ("The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter."); see, e.g., United States v. Taylor, 909 F. Supp. 355, 366-67 (M.D.N.C. 1995) (striking reference to attorneys' fee in prayer for relief where such fees were not available under the pertinent statute). As such, defendant's request to strike plaintiff's request for attorneys' fees also is granted.

3. Punitive Damages

Finally, defendant asks the court to dismiss plaintiff's claim for punitive damages. North Carolina allows punitive damages only where a plaintiff proves by clear and convincing evidence of one or more aggravating factors, such as fraud, malice, or willful or wanton conduct. See N.C. Gen. Stat. § 1D-15(a). Defendant argues that plaintiff has offered only conclusory and formulaic allegations of willful and wanton conduct, warranting dismissal under Rule 12(b)(6).

Although it is alleged in the complaint as a separate cause of action, a punitive damages claim is not technically an independent action, but is instead dependent upon an award of compensatory damages on one of plaintiff's other claims. See, e.g., Eli Research, Inc. v. United Commc'ns Grp., LLC, 312 F. Supp. 2d 748, 764 (M.D.N.C. 2004) (noting that under North Carolina

law, "claims for punitive damages and injunctive relief do not exist as unique causes of action per se"); see also N.C. Gen. Stat. § 1D-15(a) ("Punitive damages may be awarded only if the claimant proves that the defendant is liable for compensatory damages . . . ."). As this court has noted in the past, "[t]he question of whether or not a party can recover punitive damages goes to the issue of the relief the plaintiff may ultimately be due. It has no bearing on the validity of the cause of action set out in plaintiff's complaint." See Jones v. Wake County Hosp. Sys., 786 F. Supp. 538, 547 (E.D.N.C. 1991).

Accordingly, the court will not dismiss this "cause of action," but will instead consider the appropriateness of punitive damages as part of plaintiff's prayer for relief. Foreclosing an award of punitive damages under Rule 12(b)(6) at this stage of the litigation appears premature where claims remain for which such damages might be appropriate. In this respect, defendant's motion to dismiss is denied as to the prayer for punitive damages.

CONCLUSION

For the reasons set forth above, defendant's motion to dismiss (DE # 12) is GRANTED IN PART and DENIED IN PART. Plaintiff's negligent misrepresentation, fraud, and unfair and deceptive trade practices claims are DISMISSED. Plaintiff's request for attorney's fees is STRICKEN from the complaint pursuant to Rule 12(f). Plaintiff's "cause of action" for punitive damages shall be considered part of her prayer for relief, and will not be stricken. Plaintiff's remaining claims shall proceed.

SO ORDERED, this the 7th day of July, 2011.

LOUISE W. FLANAGAN
Chief United States District Judge